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To: Local and Tribal Health Departments and Health Care Providers

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Updated SARS-CoV-2 Laboratory Data Reporting Guidance Effective April 4, 2022

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Summary

New COVID-19 laboratory data reporting guidance from the U.S. Department of Health and Human Services (HHS) went into effect April 4, 2022. The Wisconsin Department of Health Services (DHS) has adopted state level reporting to align with the HHS changes. HHS still requires positive and negative results from **NAAT (RT-PCR) testing conducted in a facility certified under Clinical Laboratory Improvement Amendments (CLIA) to perform moderate or high-complexity tests** to be reported to state, territorial, local, and tribal (STLT) public health departments within 24 hours. For all other SARS-CoV-2 testing (except antibody and self-administered testing), only positive results are required to be reported. Reporting negative results from sites with a CLIA waiver to STLT public health departments is optional and no longer required. Reporting of self-administered tests is also optional. Both HHS and DHS will also no longer require testing agencies to report SARS-CoV-2 antibody test results.

Background

Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, HHS has required all laboratories performing SARS-CoV-2 testing or analysis to report the results from each test to the appropriate STLT health department. On March 8, 2022, HHS released [new laboratory data reporting guidance](#) that changed the current laboratory data reporting requirements. The Centers for Medicare and Medicaid Services (CMS) revised their *Clinical Laboratory Improvement Act Amendments of 1988 (CLIA) Laboratories Surveyor Guidance for New and Modified CLIA Requirements Related to SARS-CoV-2 Test Result Reporting (QSO-21-10-CLIA)* on April 15, 2022, to adopt these changes. This new guidance went into effect April 4, 2022, in Wisconsin and nationwide.

Effective April 4, 2022, HHS SARS-CoV-2 laboratory data reporting guidance will still require reporting of **all results from NAAT (RT-PCR) testing conducted in a facility certified under CLIA to perform moderate or high-complexity tests**. This includes all positive, negative, and inconclusive results from clinical laboratories, including public health, commercial, healthcare systems, and academic laboratories performing diagnostic NAAT testing. Per the HHS requirement, NAAT results should be reported within 24 hours of results being known to the appropriate STLT health department. **DHS will continue to require reporting of these results from NAAT testing within 24 hours [electronically through the Wisconsin Electronic Disease Surveillance System \(WEDSS\)](#)**, or by fax to the patient's local health department. Facilities who wish to have DHS report to HHS on their behalf must report test

results electronically to the WEDSS. Reporting can occur through already established electronic laboratory reporting (ELR) connections, or by establishing a web-based laboratory reporting (WLR) connection.

Facilities conducting all other SARS-CoV-2 testing (e.g., testing conducted in a setting operating under a CLIA certificate of waiver, non-NAAT testing conducted in a facility certified under CLIA to perform moderate- or high-complexity tests), excluding antibody and self-administered tests, will still be required to report positive test results to the appropriate STLT health department. Under the new guidance, reporting negative test results for these tests to STLT public health departments will no longer be required, but is optional. **DHS will continue to require positive results from rapid testing, excluding positive results from self-administered tests, to be reported.** DHS has never required the reporting of negative lab results from antigen and rapid tests. HHS did require reporting of these negative results.

As of April 4, 2022, per HHS guidelines, testing entities will not be required to report SARS-CoV-2 antibody results. **DHS will no longer require the reporting of positive or negative antibody test results.**

DHS Reporting Requirements Effective April 4, 2022

Type of SARS-CoV-2 Test	Reporting Requirements	
NAAT-testing conducted in a facility certified under CLIA to perform moderate- or high-complexity tests	Positive Test Result: Required	Negative and Inconclusive Test Result: Required
All other testing (except antibody)	Positive Test Result: Required	Negative and Inconclusive Test Result: Not Required
Antibody testing	Positive Test Result: Not Required	Negative and Inconclusive Test Result: Not required

Required Data Elements and Data Harmonization

Per HHS guidance, the following data elements must be collected and reported for SARS-CoV-2 laboratory tests (as required under Section 1) for the transmission of complete laboratory testing data to the appropriate STLT health departments. STLT health departments will send deidentified data to CDC or the Secretary's designee. (Note: Additional data elements may be requested at a future date). In Wisconsin, all results should be reported [electronically through WEDSS](#) or by fax to the patient's local health department. Facilities who wish to have DHS report to HHS on their behalf must report test results electronically to the WEDSS. Reporting can occur through already-established electronic laboratory reporting (ELR) connections, or by establishing a web-based laboratory reporting (WLR) connection.

1. Patient name (last name, first name, middle initial)*

2. Patient street address*
3. Patient phone number with area code*
4. Patient date of birth*
5. Patient age
6. Patient race
7. Patient ethnicity
8. Patient sex
9. Patient residence zip code
10. Patient residence county
11. a) Test ordered and b) test resulted– use appropriate LOINC codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC
12. Device identifier
13. Test result (values) – use appropriate SNOMED-CT codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC
14. Test result date (date format)
15. Date specimen collected (date format)
16. Accession #/Specimen ID
17. Ordering organization or ordering provider name and NPI (as applicable), address, phone number, zip code along with affiliated organization (specific facility)
18. Performing facility name and CLIA number, address, phone number, code
19. Specimen Source - use appropriate SNOMED-CT, LOINC, or SPM4 codes, or equivalently detailed alternative codes
20. Reporting entity name and CLIA number (or appropriate ID), and address.

COVID-19 Laboratory Data Reporting Guidance Resources

Laboratory Data Reporting: CARES Act Section 18115: [COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 \(cdc.gov\)](#)